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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,610	12/15/2000	Chyi-Cheng Chen	20529/111697	2197
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BRYAN CAVE LLP 1290 AVENUE OF THE AMERICAS 33RD FLOOR NEW YORK, NY 10104			EXAMINER KWON, BRIAN YONG S	
			ART UNIT 1614	PAPER NUMBER

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/738,610

Applicant(s)

CHEN ET AL.

Examiner

Brian S Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10,11 and 14-34 is/are pending in the application.
4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
5) ☐ Claim(s) 1, 3-8 and 10-11 is/are allowed.
6) ☒ Claim(s) 22-34 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary of Action

- I. The rejection of claims 22-24 and 26-34 under 35 USC 102(b) will be maintained for the reason of the record.
- II. The rejection of claims 25 under 35 USC 103(a) will be maintained for the reason of the record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 22-24 and 26-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt et al. (US 4605666).

This rejection is analogous to the rejection mailed 8/26/2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (US 4605666) in view of Hill (US 3946110).

This rejection is analogous to the rejection mailed 8/26/2003.

Response to Arguments

3. Applicant's arguments filed November 28, 2003 have been fully considered but they are not persuasive.

In response to the examiner's rejection of claims 22-24 and 26-34 under 35 USC 102(b), applicants state:

Initially, we note that the Examiner has previously expressly conceded that Schmidt does not anticipate the composition of claims 22-34. In the Office Action dated February 5, 2003, the Examiner rejected claims 1-13 and 22-34 solely under 35 U.S.C. 103(a) over Schmidt and if necessary, further view of Newlin, U.S. Patent No. 3,615,591 ("Newlin"), Chiralt et al., 1999 IFT Annual Meeting ("Chiralt"), and Hussaini et al., A Guide to Halal food Selection 1993 ("Hussaini"). (Paper No. 11 at 3.) The Examiner stated only that "[t]his rejection is analogous to the original rejection" found in the Office Action dated June 26, 2002. (*Id.* citing Paper No. 9.)

In Paper No. 9, the Examiner acknowledged that "*Schmidt differs from the claimed invention in* 1) the specific amounts of pectin in the composition, about 0.1 to about 10%, more specifically about 0.5 to 5%, based on the total weight of the composition; 2) 95-99% by weight of L-ascorbic acid and/or a pharmaceutically acceptable salt; 3) the use of citrus pectin; and 4) the functional characteristic of pectin as a binder." (Paper No. 9 at 4; See also, Paper No. 3 at 4.)

The claims have not changed since Paper No. 11, nor has Schmidt changed. Nor has the Examiner explained the apparent discrepancy between Paper Nos. 9 and 11 and the present Office Action. Thus, the record reflects an unambiguous admission that there are at least four differences between claims 22-24 and 26-34 and Schmidt. For this reason alone, the rejection should be withdrawn.

If the PTO desired to assert a § 102 rejection of claims 22-24 and 26-34 based on Schmidt, the time to have done so was in Paper No. 11 – the Office Action following the September 22, 2002 Response presenting those claims. The § 102 rejection is nothing more than a belated attempt to rewrite the history of this prosecution, which spans three years. This rejection is contrary to the PTO's stated policies and is a text book example of piecemeal prosecution clearly frowned upon by the PTO. "Piecemeal examination should be avoided as much as possible. The examiner ordinarily should reject each claim on all valid grounds available, avoiding, however, undue multiplication of references." MPEP 707.07(g) (8th Ed., Rev. 1, February 2003, p. 700-116.) For this reason also, the rejection should be withdrawn.

Although the examiner acknowledges that there has been a change in the examiner's applying of Schmidt (US 4605666) as a reference qualified under 35 USC 102(b) which the

examiner had previously applied as 35 USC 103(a) reference, however, the applicant's argument is irrelevant to the merits of the case. It is unfortunate situation that the examiner's view had been changed during the prosecution of the instant application, however, this is not same as the alleged "unambiguous admission that there are at least four differences between claims 22-24 and 26-34 and Schmidt". As stated above, the alleged argument is irrelevant to the merits of the case. Therefore, no response is made to this argument by the examiner.

Applicant's argument takes position that Schmidt fails to disclose "each and every element" of the claimed compositions, namely "a composition having a compressibility superior to a composition comprising...a standard binder". Applicants allege that not one of the exemplified embodiments of Schmidt discloses the use of pectin as binder or as an excipient.

With respect to "the functional characteristic of using pectin as a binder", the examiner agrees with the applicants that Schmidt is silent about such property or characteristic. However, the examiner maintains that the property or characteristic is deemed to be inherent to the composition. Especially in view of overlapping dosage amount "less than three percent" of excipient (i.e., pectin) disclosed in Schmidt, the alleged property must be inherently presented in the composition. Claims to a composition possessing a particular property of characteristic are still properly rejected by a reference to the same composition, even if the reference does not address or acknowledge the property. Anticipation under 35 USC 102 is an essentially irrebuttable question of fact, wherein the court stated that anticipation "cannot be overcome by evidence of unexpected results or teachings away in the art". *In re Malagari*, 499 F.2d 1289, 182 USPQ; *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); *In re Fracalossi*, 681 F.2d 792, 215 USPQ 569 (CCPA 1982); *In re Alternpohl*, 500 F.2d 1151, 183 USPQ 38 (CCPA 1974); *In re Wiggins*, 488 F.2d 538, 179

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USPQ 421 (CCPA 1973); In re Wilder, 429 F.2d 447, 166 USPQ 545 (CCPA 1970). Indeed, a reference might reside in a nonanalogous art and yet constitute an anticipation of a claimed invention under 35 USC 102. *In re Self, 571 F.2d 134, 213 USPQ 1 (CCPA 1982)*.

Since the instant claims allows for the inclusion of any other unspecified ingredients in said composition by reciting open transitional phrases such as “comprising” in the claim, the Schmidt anticipates the claimed invention. One of ordinary skill in the art is able to “at once envisage” the claimed composition within the sufficiently limited or well-delineated components and their dosage ranges, the composition is anticipated.

In response to the examiner’s rejection of claim 25 under 35 USC 103(a), applicants states:

As is well settled, the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

Initially we note that the rejection uses the wrong standard for determining obviousness. The rejection relies upon three different standards in making the rejection:

- 1) “[t]o incorporate such teaching ... would have been obvious;
- 2) [o]ne ... would have expected ... that citrus pectin would be preferred;

and

- 3) one ... would have been motivated to modify

However, none of these standards is found in the statute or precedential authority. Because the rejection used the wrong standard, it should be withdrawn for this reason alone.

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As set forth above, the rejection based on Schmidt alone is insufficient under § 102 and § 103. And, the Examiner has identified no disclosure in Hill to remedy these fatal factual deficiencies. Indeed, the Examiner relies on Hill solely for its disclosure of a citrus pectin. Because the rejection is factually deficient, it must fail for this reason also. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). (When a conclusion of obviousness is not based upon facts, it cannot stand.)

As we discussed above, the Examiner has already admitted on the record that Schmidt has at least four factual gaps that prevent it from being cited alone under § 102 or § 103. (See Paper No. 9 at 4.) The Examiner sought to fill these gaps using Newlin, Chiralt, and/or Hussaini. (Paper No. 11 at 4.) In the present Office Action, the rejection based on Schmidt in view of Newlin, Chiralt, and/or Hussaini has been withdrawn. Withdrawal of this rejection is an admission that the Newlin, Chiralt, and Hussaini gap fillers in combination were insufficient to render the claims unpatentable. It stands to reason that Hill alone, which is relied on solely for its disclosure of a citrus pectin, is also insufficient to reject the claims – here claim 25.

Similarly to the above comments, the applicants' argument deems to be irrelevant to the merits of the case. The instant claim has been rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (US 4605666) in view of Hill (US 3946110) in which the rejection was issued as a new ground of rejection in response to applicants' filing of the instant application as RCE. Applicant's discussion of the references cited in Paper No. 9 and 11 (namely Newlin, Chiralt, and/or Hussaini) and "at least four factual gaps that prevent it from being cited under 102 or 103" are irrelevant to the merits of the case. Furthermore, applicants' alleged "the wrong standard for determining obviousness" or "none of these standards is found in the statute or precedential authority" is irrelevant to the merits of the case. Therefore, no response is made to this argument by the examiner.

Applicants' argument takes position that Hill does not provide data or technical reasoning to suggest that acetylsalicylic acid would behave in a similar manner as ascorbic acid when combined with pectin, therefore, there is no motivation to combine Hill with Schmidt. The examiner disagrees with this argument. Unlike applicants' allegation, the skill artisan would have looked into the similar properties and utilities of pectin and citrus pectin in preparing medicinal tablet composition. The skill artisan would have known that pectins are natural plant hydrocolloids derived from edible fruits and vegetables, including apples and citrus fruits and expected that any pectins (whatever their origin-from fruits or vegetables) would behave similarly. Therefore, one having ordinary skill in the art would have been motivated to modify the teaching of Schmidt, with the reasonable expectation of success, such that said composition can be readily formed into tablet when it is compressed.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Claims 1, 3-8 and 10-11 are allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (571) 273-0584. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

Zohreh Fay